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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,719	01/13/2004	Mark E. Cook	960296.00108	2648
27114 7590 08/14/2007 QUARLES & BRADY LLP 411 E. WISCONSIN AVENUE, SUITE 2040 MILWAUKEE, WI 53202-4497			EXAMINER ARNOLD, ERNST V	
			ART UNIT 1616	PAPER NUMBER
			NOTIFICATION DATE 08/14/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

Office Action Summary	Application No. 10/756,719	Applicant(s) COOK ET AL.	
	Examiner Ernst V. Arnold	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 5-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 5-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 2 and 4 have been cancelled. Claims 3 and 5-16 are pending and under examination.

Withdrawn rejections:

Claims 3 and 5-16 were rejected under 35 U.S.C. 112, first paragraph. Applicant has amended the claims and the Examiner withdraws the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3 and 5-16 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 6,395,782) in view of Horrobin et al. (US 6,245,811).

Applicant claims a method of treating rheumatoid arthritis by administering conjugated linoleic acid.

Determination of the scope and content of the prior art**(MPEP 2141.01)**

Cook et al. teach methods of extending the survival time of a human or non-human animal having a disease, thus in need of treatment, characterized by autoimmune complexes by administering an effective amount of conjugated linoleic acid (Claim 1). Cook et al. teach isomers of conjugated linoleic acid (column 4, lines 40-45). Cook et al. teach methods suitable for treating rheumatoid arthritis (column 3, lines 37-60). Cook et al. teach feeding, thus oral administration, mice diets of conjugated linoleic acid and corn oil (column 4, lines 49-54). It is the Examiner's position that corn oil can serve as a carrier. Cook et al. teach conjugated linoleic acid in the range of about 0.05% to about 2.0% in the diet or about 0.1 to 10g/day (column 4, lines 15-20).

Horrobin et al. teach and suggest a method for treating a disorder (rheumatoid arthritis) comprising administering to a patient in need thereof an effective amount of the compound according to claim 1 where R_1 is an acyl moiety corresponding to an acid (conjugated linoleic acid) (Column 14 lines 55-62; column 15, line 1 and claims 1, 10 and 28). The Examiner interprets the compound to be an ester of conjugated linoleic acid. Doses may be administered to the patient in need thereof orally, enterally, topically, parenterally, (subcutaneously, intramuscularly, intravenously), rectally, vaginally or by any other appropriate route (Column 17, lines 32-36 and claim 28). By patient, the Examiner interprets this to be a human. Horrobin et al. teach that the compound can be in a food or nutritional supplement (Claim 40).

Horrobin et al. disclose in claim 28 a method of treating a disorder selected from the group consisting of...rheumatoid arthritis...comprising administering to a patient in need thereof

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an effective amount of the compound of claim 10. Horrobin et al. disclose in claim 10 a compound according to claim 1 where R1 is an acyl moiety corresponding to...conjugated linoleic acid. Therefore, it is the Examiner's position that Horrobin et al. teach or suggest a method of treating rheumatoid arthritis with a compound containing conjugated linoleic acid.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Cook et al. do not expressly teach a method wherein the conjugated linoleic acid is an ester of a conjugated linoleic acid.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use an ester of conjugated linoleic acid, as suggested by Horrobin et al., in the method of treating rheumatoid arthritis as taught by Cook et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Horrobin et al. suggests that esters of conjugated linoleic acid can be used in a method of treating rheumatoid arthritis. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) A reference is good not only for what it teaches by direct anticipation but also for

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what one of ordinary skill in the art might reasonably infer from the teachings. (In re Opprecht 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); In re Bode 193 USPQ 12 (CCPA) 1976).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant asserts that Cook et al. did not teach that CLA can reduce the symptoms of arthritis much less the specific symptoms of joint redness and swelling of rheumatoid arthritis but does agree that Cook et al. indicate treatment of subjects with conditions that include rheumatoid arthritis. It is the Examiner's position that treatment of a condition does reduce the symptoms of the condition otherwise it would not be a treatment of the condition. Thus, administering conjugated linoleic acid to the patient would reduce the symptoms of rheumatoid arthritis including joint inflammation resulting in improvement of joint redness and swelling.

The reference of Horrobin et al. is relied upon for the teaching of treatment of rheumatoid arthritis with esters of conjugated linoleic acid. Horrobin et al. teach and suggest treating

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rheumatoid arthritis with conjugated linoleic acid. Applicant asserts "the reasonable way of reading of the sections cited by the Examiner would be that a compound can be used to treat one or more diseases listed there for which the compound was known to be effective at the time the Horrobin et al. application was filed but not that a compound can be used to treat all of the diseases listed." This is a good argument except the reference of Cook et al. specifically teaches treatment of rheumatoid arthritis with only conjugated linoleic acid. It is then simple for one of ordinary skill in the art to conclude that rheumatoid arthritis can be treated with esters of CLA because the art teaches treatment of rheumatoid arthritis with CLA. Applicant's arguments are not persuasive.

Applicant asserts that one of ordinary skill in the art would not have had a reasonable expectation of success that CLA can reduce the symptoms of arthritis at the time the application was filed (1/13/2004). The Examiner cannot agree. Reduction of symptoms is intrinsic to the method of treatment and the art teaches treatment of rheumatoid arthritis with CLA. One would expect a reduction of symptoms during the course of treatment.

Applicants' arguments are not persuasive. The rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

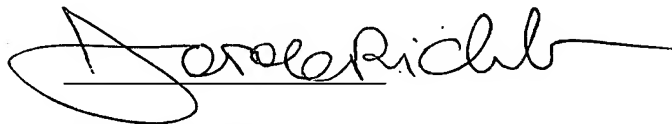
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
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A handwritten signature in black ink, appearing to read "Johann R. Richter", with a large, stylized loop at the beginning.

Johann R. Richter
Supervisory Patent Examiner
Technology Center 1600